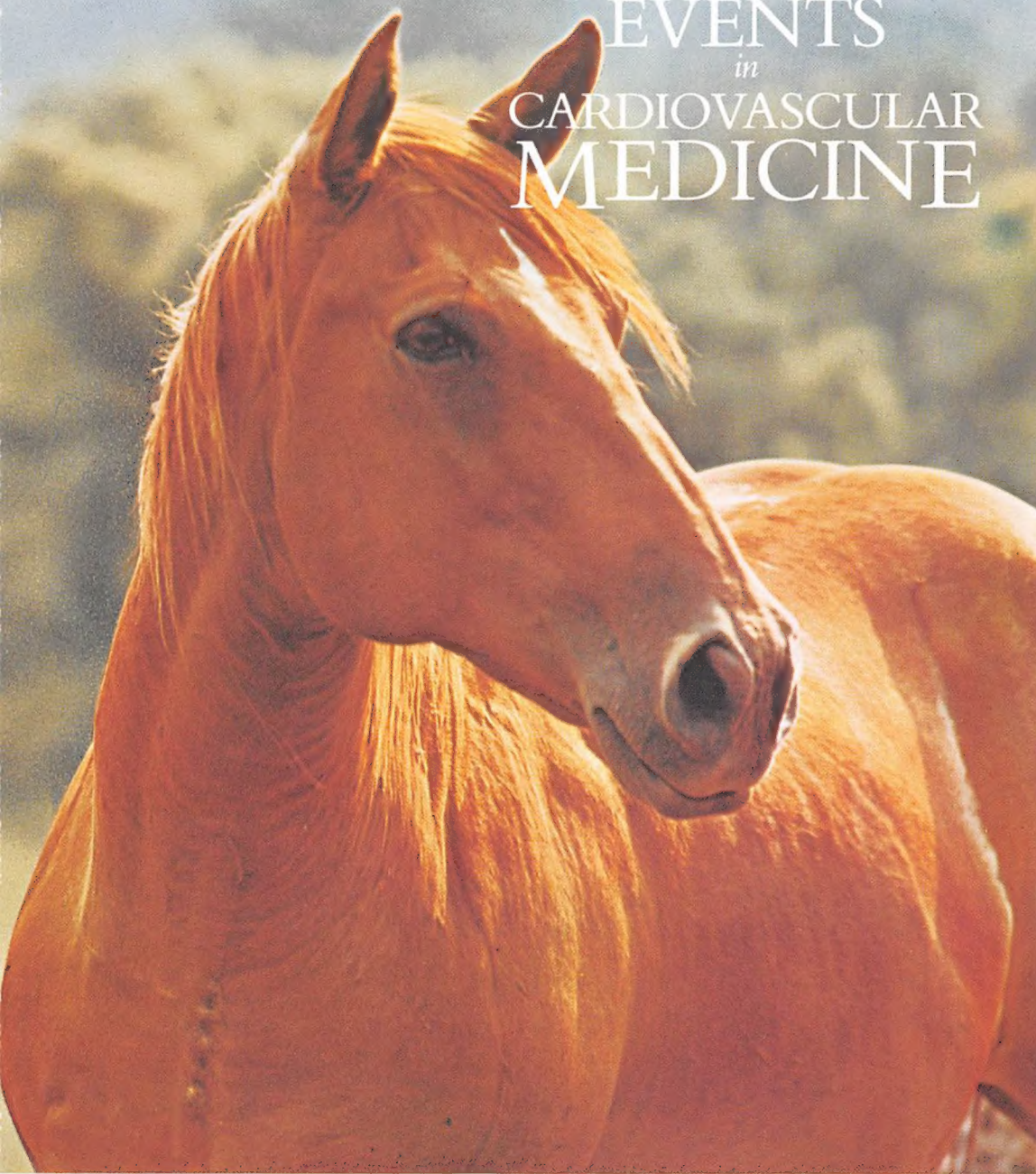


IMPORTANT
EVENTS
in
CARDIOVASCULAR
MEDICINE



Professional Use Information

NITRO-BID® Plateau CAPS®

(nitroglycerin) 2.5 mg, 6.5 mg, 9 mg

Description: Each NITRO-BID® Controlled-Release Capsule contains: 2.5 mg nitroglycerin: Light purple and clear capsule with white beads; identification imprint MARION/1550. 6.5 mg nitroglycerin: Dark blue and yellow capsule with white beads; identification imprint MARION/1551. 9 mg nitroglycerin: Green and yellow capsule with white beads; identification imprint MARION/1553.

Also contains: calcium stearate, lactose, silica gel, starch, croscellose, talc, and other ingredients.

Action: The mechanism of action of nitroglycerin in the relief of angina pectoris is not as yet known. However, its main pharmacologic action is to relax smooth muscle, principally in the smaller blood vessels, thus dilating arterioles and capillaries, especially in the coronary circulation. In therapeutic doses, nitroglycerin is thought to increase the blood supply to the myocardium which may, in turn, relieve myocardial ischemia, the possible functional basis for the pain of angina pectoris. The sublingual administration of nitroglycerin is normally rapid and transient, but nitroglycerin in controlled-release NITRO-BID® 2.5, NITRO-BID® 6.5, and NITRO-BID® 9 produces a prolonged action.

Indications: Based on a review of this drug and a related drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the indications as follows:

“Possibly” effective: For the management, prophylaxis, or treatment of anginal attacks.

Final classification of the less-than-effective indications requires further investigation.

Contraindications: Acute or recent myocardial infarction, severe anemia, closed-angle glaucoma, postural hypotension, increased intracranial pressure, and idiosyncrasy to the drug.

Warnings: Capsules must be swallowed. FOR ORAL, NOT SUBLINGUAL, USE. NITRO-BID® 2.5, NITRO-BID® 6.5, and NITRO-BID® 9 Controlled-Release Capsules are not intended for immediate relief of anginal attacks.

Precautions: Intraocular pressure may be increased; therefore, caution is required in administering to patients with glaucoma. Tolerance to this drug and cross-tolerance to other organic nitrites and nitrates may occur. If blurring of vision, dryness of mouth, or lack of benefit occurs, the drug should be discontinued.

Adverse Reactions: Severe and persistent headaches, cutaneous flushing, dizziness, and weakness. Occasionally, drug rash or exfoliative dermatitis and nausea and vomiting may occur; these responses may disappear with a decrease in dosage. Adverse effects are enhanced by ingestion of alcohol, which appears to increase absorption from the gastrointestinal tract.

Dosage and Administration: Administer the smallest effective dose two or three times daily at 8- to 12-hour intervals, unless clinical response suggests a different regimen. Patient should be titrated to anginal relief or hemodynamic response. Hemodynamic response can be measured by drop in systolic blood pressure. Discontinue if not effective.

How Supplied: NITRO-BID® (nitroglycerin) 2.5, 6.5, and 9 Controlled-Release Capsules are available in 60- and 100-count bottles.

Caution: Federal law prohibits dispensing without prescription.

Storage: Store at a controlled room temperature. Dispense only in the original unopened container.

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